

INFORMATION NOTICE

TO: Department of Health and Family Services
Radioactive Material Medical Use Licensees

FROM: Department of Health and Family Services
Radioactive Materials Program

DATE: June 9, 2005

SUBJECT: Information Notice concerning MICK[®] Applicators

PURPOSE:

The Wisconsin Department of Health and Family Services is issuing this information notice to inform medical use licensees of recent incidents involving jamming of the MICK[®] Applicator. It is expected that recipients will review this information for applicability to their licensed activities and consider actions, as appropriate, to avoid similar problems. Suggestions contained in this Information Notice are not new DHFS requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

During the period of April 1, 2005 to June 1, 2005, the Department of Health and Family Services became aware of two incidents in which a MICK[®] Applicator jammed resulting in a Pd-103 seed being ruptured.

In the first incident, the Radiation Oncologist after changing cartridges encountered resistance when implanting the first seed. The Radiation Oncologist was then unable to insert the stylete (i.e., plunger) more than a few millimeters when trying to implant the second seed. Upon trying to remove the cartridge to investigate the problem, a Pd-103 brachytherapy prostate seed broke.

In the second incident, the Radiation Oncologist after changing cartridges encountered a similar problem. The implantation needle became detached from the MICK[®] Applicator during the process of trying to install a new cartridge. After reattaching the implantation needle, the Radiation Oncologist attempted to implant the first seed. However, the stylete would not insert more than a few millimeters. The Radiation Oncologist then attempted to remove the cartridge to investigate why the applicator had jammed. In the process of removing the cartridge, a Pd-103 brachytherapy prostate seed broke, resulting in the spread of contamination.

In discussions with other licensees, the Nuclear Regulatory Commission and other Agreement States, it was discovered that there have been other reported cases involving the MICK[®] Applicator becoming jammed. In some cases, the licensees were able to get the applicators working again and in other cases the prostate seeds have broken.

DISCUSSION

Failure to perform preventative maintenance on the MICK[®] Applicator may be the cause for jamming incidents. Licensees are reminded that they should perform the manufacturer's recommended preventative maintenance on the MICK[®] Applicator.

Licensees are also reminded not to screw cartridges into or out of the MICK[®] Applicator. Both the reusable and disposable cartridges are designed to seat in the MICK[®] Applicator by simply pushing them into the magazine receptor with a noticeable click.

Licensees should also be aware that the 'Disposable MICK[®] Cartridge' maximum seed capacity is 15 seeds. The maximum seed capacity for the 'Reusable MICK[®] Cartridge' is 10 seeds. If loading more than the maximum seed capacity, the applicator could jam. In addition, the 'Shielded / Disposable MICK[®] Magazines' are designed for one time use **ONLY**.

The MICK[®] web site at <http://www.micknuclear.com> contains information on dislodging jammed seeds. An excerpt from the web site is included for your information.

This Information Notice requires no specific action or written response. If you have any question about the information in this notice, please contact Cheryl K. Rogers at (608) 266-8135 or email at rogerck@dhfs.state.wi.us or Jason Hunt at (608) 266-9443 or email at huntjh@dhfs.state.wi.us.

Implant Sequence - (Continued)

Recommended

Useful Tips During the Implant Process:

When Loading the Magazine into the Applicator, ensure the Magazine sets into the Applicator properly, loading with a noticeable “Click”.

Ensure the needle is properly connected to the Applicator. The needle should “CLICK” into the Needle Receptor and should not disconnect unless the Needle Release Button is depressed.

During implantation, ensure the seed is completely advanced through the needle. Do not advance the seed partially out of the cartridge and retract the Push-Wire Rod. This may cause the seeds to drop unevenly and seeds may become jammed in the cartridge.

When loading Mick Magazines, visually check that the seeds are loaded straight and even in the cartridge. If the seeds are placed askew in the cartridge, it may cause jamming during the implant procedure.

After an implant procedure, it is strongly recommended a physical seed inventory be performed to account for all seeds.

Dislodging Jammed Seeds:

If and when a seed is jammed between the Applicator Needle Chuck and the Seed Cartridge, DO NOT force the seed Magazine out of the Magazine receptor area of the Applicator. Undue pressure on the seeds may cause the seeds to break or fracture.

The following techniques can be attempted:

- ◆ Partially unscrew the head of the magazine (**no more than one turn**), thereby relieving the downward pressure on the seeds. Please note that the Magazine Head and the cartridge are **NOT** designed or intended to be taken apart. This is only done to relieve the spring pressure on the seeds. Carefully attempt to remove the Magazine from the Applicator.
- ◆ Flush the jammed seed out of the Applicator using a light pressure water flush. This must be done over a collection pan situated such that all seeds are collected and accounted for. If the seeds cannot be removed safely, place the Applicator in quarantine. The Applicator must be surveyed (for radiation) to determine if the broken seed has contaminated the Applicator.

If contaminated, the Applicator must remain in quarantine for a minimum of 10 half-lives.

If clean, it is recommended that the Applicator be returned to the manufacturer for evaluation and repair/adjustment.

Returning an Applicator for Service or Repair:

1. Call MRNI, Inc., Customer Service Tel. 914-667-3999 to obtain a “Return Authorization” number.
2. Mick Applicators (Instrument only) must be sterilized before sending to MRNI, Inc.
3. MRNI, Inc. will fax you form #414-10 to be completed by you (without the proof of a decontamination form, your Mick Applicator will be returned unserviced).

Upon MRNI’s Receipt of Mick Applicator:

The Mick Applicator will be analyzed to determine the extent of the repair. We will then call the Contact Person to get authorization for repair and cost before we commence with any work. The Mick Applicator will be returned prior to your next case date.